Notice of Allowability	Application No.	Applicant(s)	
	10/660,101	BOTT ET AL.	
	Examiner	Art Unit	
	Lora E. Barnhart	1651	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to *the RCE filed 11/24/06*.

2. ☒ The allowed claim(s) is/are *56,62-66 and 68-86*.

3. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
   a) ☐ All b) ☐ Some* c) ☐ None of the:
      1. ☐ Certified copies of the priority documents have been received.
      2. ☐ Certified copies of the priority documents have been received in Application No. _____ .
      3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

   * Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.
THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

4. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.

5. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
   (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
      1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
   (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

   Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).

6. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO/SB/08), Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application
6. ☐ Interview Summary (PTO-413), Paper No./Mail Date _____ .
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____.

EXAMINER'S AMENDMENT

An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Tim Hagan on 1/29/07.

The application has been amended as follows:

At page 14, line 20, of the as-filed specification, insert - - - protease - - - after the word "*subtilis*".

At page 44, line 5, of the as-filed specification, insert - - - protease - - - after the word "*subtilis*".

Replace claim 56 in its entirety with the following:

- - - 56. A method of removing necrotic tissues from the skin of a patient in need thereof comprising:

providing a topical preparation, wherein said topical preparation comprises an internal phase and an external phase,

wherein said internal phase is dispersed within said external phase,

wherein said internal phase comprises at least one hydrophilic carrier, at least one hydrophilic component containing water, and at least one active agent comprising an enzyme, and

wherein said external phase comprises a silicone matrix; and

contacting said topical preparation with the necrotic tissue on the skin of said patient, such that said active agent is released from said silicone matrix onto said necrotic tissue on the skin,

wherein said enzyme removes said necrotic tissues upon said release.

Cancel claims 57 and 58.

Replace claim 66 in its entirety with the following:

- - -66. The method as claimed in claim 56 wherein:

said topical preparation has an occlusivity to fluid;

said occlusivity to fluid promotes a moist environment that allows swelling of necrotic tissues covered by said topical preparation such that said necrotic tissues become swollen; and

said active agent released from said silicone matrix selectively removes said swollen necrotic tissues.- - -

Cancel claim 67.

In claim 72, line 21, replace "said necrotic tissue" with the following:

- - -said necrotic tissue;

wherein said active agent removes necrotic tissue.- - -

Replace claims 74 and 75 in their entirety with the following:

- - - 74. A method of removing necrotic tissues from the skin of a patient in need thereof comprising:

providing a topical preparation, wherein said topical preparation comprises an internal phase and an external phase,

wherein said internal phase is dispersed within said external phase,

wherein said internal phase comprises at least one hydrophilic carrier, at least one hydrophilic component containing water, and at least one active agent comprising LG12 protease, and

wherein said external phase comprises a silicone matrix; and

contacting said topical preparation with the necrotic tissues on the skin of said patient, such that said LG12 protease enzyme is released from said silicone matrix onto said necrotic tissues on the skin,

wherein said LG12 protease enzyme removes said necrotic tissues upon said release.

75. The method as claimed in claim 74 further comprising:

providing a second topical preparation comprising an internal phase and external phase,

wherein said internal phase is dispersed within said external phase,

wherein said internal phase comprises at least one hydrophilic carrier, at least one hydrophilic component containing water, and an LG12 protease enzyme inhibitor, and

wherein said external phase comprises a silicone matrix; and

wherein said silicone matrix comprises a silicone adhesive; and

placing said second topical preparation on said skin of said patient around a wound comprising necrotic tissues on said skin and adhering said first topical preparation over said wound by contacting said first topical preparation to said second

topical preparation, such that the skin around the wound is protected from said LG12 protease enzyme.- - -

Add the following new claims 76-86:

- - - 76. A method of cleansing a wound on the skin of a patient in need thereof comprising:

providing a topical preparation, wherein said topical preparation comprises an internal phase and an external phase,

wherein said internal phase is dispersed within said external phase,

wherein said internal phase comprises at least one hydrophilic carrier, at least one hydrophilic component containing water, and at least one active agent comprising LG12 protease enzyme, and

wherein said external phase comprises a silicone matrix; and

contacting said topical preparation with the wound on the skin of said patient, such that said LG12 protease enzyme is released from said silicone matrix onto said wound on the skin,

wherein said LG12 protease enzyme cleanses said wound upon said release.- - -

77. The method as claimed in claim 76 further comprising:

providing a second topical preparation comprising an internal phase and external phase,

wherein said internal phase is dispersed within said external phase,

wherein said internal phase comprises at least one hydrophilic carrier, at least one hydrophilic component containing water, and an LG12 protease enzyme inhibitor, and

wherein said external phase comprises a silicone matrix; and

wherein said silicone matrix comprises a silicone adhesive; and

placing said second topical preparation on said skin of said patient around a wound comprising necrotic tissues on said skin and adhering said first topical preparation over said wound by contacting said first topical preparation to said second topical preparation, such that the skin around the wound is protected from said LG12 protease enzyme.

78. A method of cleansing a wound on the skin of a patient in need thereof comprising:

providing a topical preparation, wherein said topical preparation comprises an internal phase and an external phase,

wherein said internal phase is dispersed within said external phase,

wherein said internal phase comprises at least one hydrophilic carrier, at least one hydrophilic component containing water, and at least one active agent comprising an enzyme, and

wherein said external phase comprises a silicone matrix; and

contacting said topical preparation with the wound on the skin of said patient, such that said active agent is released from said silicone matrix onto said wound on the skin,

wherein said enzyme cleanses said wound upon said release.

79. The method as claimed in claim 78 wherein said silicone matrix is selected to have a cross-link density suitable for providing a desired rate of active agent release from said silicone matrix.

80. The method as claimed in claim 78 wherein said hydrophilic component is selected such that said active agent is released from said silicone matrix at a desired rate.

81. The method as claimed in claim 78 wherein said topical preparation comprises a patch having a thickness, and wherein said thickness of said patch is selected such that said active agent is released from said silicone matrix at a desired rate.

82. The method as claimed in claim 78 wherein said topical preparation has an occlusivity to air, and wherein said occlusivity to air of said topical preparation is selected such that said active agent is released from said silicone matrix at a desired rate.

83. The method as claimed in claim 78 wherein said at least one hydrophilic carrier comprises polypropylene glycol.

84. The method as claimed in claim 78 wherein said at least one active agent comprises at least one hydrolase enzyme.

85. The method as claimed in claim 84 wherein said hydrolase enzyme is selected from lipases and proteases.

86. The method as claimed in claim 85 wherein said protease comprises LG12. - -

Basis for the above amendments to the specification may be found in U.S. Patent 5,677,163, which was incorporated by reference into the instant application. U.S. '163 discloses the sequence of LG12 protease (Figure 1; columns 1 and 2) and a manner of preparing the same (column 4, line 35, through column 5, line 39), and characterizes LG12 protease as a subtilisin, which is a proteolytic enzyme (column 2, lines 48-57; column 4, line 35; column 5, lines 26-28, *inter alia*).

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Lora E. Barnhart whose telephone number is 571-272-1928. The examiner can normally be reached on Monday-Thursday, 9:00am - 5:30pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G. Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Lora E Barnhart

leb

IRENE MARX
PRIMARY EXAMINER